UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

JOSEPH DIGIACINTO,

Plaintiff,

v.

RB HEALTH (US) LLC,

Defendant.

Case No. 22-cv-04690-DMR

ORDER ON DEFENDANT'S MOTION FOR JUDGMENT ON THE PLEADINGS

Re: Dkt. No. 55

Plaintiff Joseph DiGiacinto filed this putative class action against Defendant RB Health (US) LLC ("RB Health") alleging false, misleading, and deceptive marketing practices with respect to the labeling of its "Children's Delsym Cough Relief" product. RB Health moves pursuant to Federal Rule of Civil Procedure 12(c) for judgment on the pleadings. [Docket No. 55.] This matter is suitable for resolution without a hearing. Civ. L.R. 7-1(b). For the following reasons, the motion is denied.

I. DISCUSSION

The court incorporates by reference its summary of the allegations in DiGiacinto's amended complaint from the April 11, 2023 Order denying RB Health's motion to dismiss and assumes familiarity with those allegations here. *See DiGiacinto v. RB Health (US) LLC*, No. 22-CV-04690-DMR, 2023 WL 2918745, at *1-2 (N.D. Cal. Apr. 11, 2023). RB Health now moves for judgment on the pleadings based on its second affirmative defense: that DiGiacinto's claims are expressly preempted by federal law. Mot. 7-14. It also argues that DiGiacinto asserts "deceptive by implication" claims that are not viable under California law. *Id*. at 14-16.

A. Legal Standard

A Rule 12(c) motion for judgment on the pleadings "is properly granted when, accepting all factual allegations in the complaint as true, there is no issue of material fact in dispute, and the

moving party is entitled to judgment as a matter of law." *Chavez v. United States*, 683 F.3d 1102, 1108 (9th Cir. 2012). "Rule 12(c) is functionally identical to Rule 12(b)(6) and . . . the same standard of review applies to motions brought under either rule." *U.S. ex. rel. Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1054 n.4 (9th Cir. 2011). Accordingly, the "court must assess whether the complaint 'contains sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" *Chavez*, 683 F.3d at 1108 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). "When considering a motion for judgment on the pleadings, th[e] court may consider facts that 'are contained in materials of which the court may take judicial notice.'" *Heliotrope Gen., Inc. v. Ford Motor Co.*, 189 F.3d 971, 981 n.18 (9th Cir. 1999) (quoting *Barron v. Reich*, 13 F.3d 1370, 1377 (9th Cir. 1994)).

1. Preemption

With respect to preemption, RB Health argues that DiGiacinto's state law claims challenging the labels of the Children's Delsym Cough Relief product (the "children's product") are expressly preempted by the federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-399i. It contends that the Food and Drug Administration (FDA) approved the labels on the children's product and the Delsym Cough Relief product (the "adults' product") pursuant to a New Drug Application ("NDA") and Supplemental New Drug Applications ("sNDA"), and that the "FDA-approved labels have been changed" only "in minor ways since 2014." Mot. 4-5. RB Health argues that DiGiacinto's claims are preempted "because the FDA specifically approved the labels of both Products, and in so doing found the Products are not 'false or misleading in any particular.'" *Id*. at 1 (quoting 21 U.S.C. § 352(a)(1)).

RB Health filed a request for judicial notice ("RJN") with its opening brief in which it asks the court to take judicial notice of 11 documents pertaining to its preemption argument, two of which are FDA guidance materials. The remaining documents are records from the FDA related to the NDA and sNDAs for the products at issue in this case. [Docket No. 55-1 (RJN) Exs. 1-11.] RB Health states that all of the documents "are publicly available on the FDA's website or through a Freedom of Information Act [FOIA] request," although it does not describe any FOIA request. [Docket No. 55-13 (Spoerl Decl. June 22, 2023) ¶ 2.] RB Health generally argues that

the court may take "judicial notice of records and reports of administrative bodies" and cites district court cases in which courts have taken judicial notice of FDA materials. RJN 2.

Federal Rule of Evidence 201 governs judicial notice. Under Rule 201, a court may take judicial notice of "an adjudicative fact if it is 'not subject to reasonable dispute.'" *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 999 (9th Cir. 2018) (quoting Fed. R. Evid. 201(b)). A fact is "not subject to reasonable dispute" if it is "generally known," or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). However, "accuracy is only part of the inquiry under Rule 201(b)." *Khoja*, 899 F.3d at 999. "Just because [a] document itself is susceptible to judicial notice does not mean that every assertion of fact within that document is judicially noticeable for its truth." *Id.* If a court takes judicial notice of a document, it must identify the specific fact or facts it is noticing from the document. *Id*. Further, "[i]t is improper to judicially notice a [document] when the substance of the [document] is subject to varying interpretations, and there is a reasonable dispute as to what the [document] establishes." *Id*. at 1000 (internal quotation marks and citation omitted)).

RB Health's RJN includes a basic description of each exhibit in chart form and brief argument regarding the relevance of the materials. However, it does not address the relevance of each individual exhibit. More importantly, it does not identify precisely what fact or facts in each exhibit it asks the court to judicially notice, or whether it asks the court to simply take notice of the existence of the Exhibits. *See* generally RJN.

DiGiacinto opposes the RJN as to Exhibits 7-11, which are letters from the FDA to third parties[1] and what RB Health describes as "approved labeling" for the NDA and sNDAs in question. DiGiacinto argues that judicial notice of these materials is inappropriate because "Defendant attempts to use them for their purported truth and to suggest that the documents demonstrate that the FDA pre-approved the challenged children-specific labeling." [Docket No.

[1] Some of the exhibits attached to RB Health's RJN consist of communications between the FDA and third parties, including Pennwalt Corporation, Celltech Pharmaceuticals, Inc., and Reckitt Benckiser Inc. RB Health explains that "NDA 18-658 has been owned by many corporations throughout its history," and is now owned by RB Health, Mot. 3 n.1, but this statement is unsupported.

58-4 (Opp'n to RJN) 2.] He also disputes RB Health's interpretations of and the completeness of these materials. *Id*. at 2-4. For example, RB Health offers Exhibit 10, an undated letter from the FDA to Reckitt Benckiser LLC, to argue that the FDA approved changes to the labeling of the children's product following submission of an sNDA in 2013 and amendments thereto in 2014. *See* Mot. 4. However, as DiGiacinto correctly notes, Exhibit 10 does not include the labeling that was approved. DiGiacinto also contends that RB Health did not produce the 2014 sNDA, "so it is unclear what exact changes were requested or approved." Opp'n to RJN 4. Exhibit 10 also refers to an "approval letter dated June 19, 2014 which contained the following error: The labeling images in the attached labeling were incorrect," so the exhibit itself is confusing. RJN Ex. 10.

RB Health's failure to provide a clear explanation of which facts in Exhibits 7-11 it contends are judicially noticeable precludes the court's ability to evaluate DiGiacinto's objections and ultimately to determine whether the unspecified facts are subject to judicial notice.

RB Health also submitted a supplemental RJN with its reply in which it asks the court to take judicial notice of four additional exhibits, Exhibits 12-15. [Docket No. 62-4.] While it explains the relevance of each exhibit, RB Health again failed to identify which facts in the materials it contends are judicially noticeable. Moreover, "[n]ew evidence submitted as part of a reply is improper because it does not allow the [opposing party] an adequate opportunity to respond." *Townsend v. Monster Beverage Corp.*, 303 F. Supp. 3d 1010, 1027 (C.D. Cal. 2018) (quotation marks and citation omitted).

RB Health later submitted a third RJN more than five weeks after it filed its reply, to which DiGiacinto objected. [Docket Nos. 68 (2d Supp. RJN), 71.] It asks the court to take judicial notice of a December 2013 letter that appears to respond to DiGiacinto's argument that Exhibit 10 is incomplete and/or lacking complete context. According to RB Health, it identified the document after it filed its motion for judgment on the pleadings. 2d Supp. RJN 1 n.1. This submission violated Local Rule 7-3(d), which states that "[o]nce a reply is filed, no additional memoranda, papers or letters may be filed without prior Court approval, except" objections to

reply evidence and statements of recent decision.[2]

RB Health's preemption argument relies entirely on materials outside the complaint that it contends are judicially noticeable. However, as set forth above, its original RJN was deficient as it did not identify the specific facts it contends are judicially noticeable in the documents. It is not the court's responsibility to comb through its submissions to try to determine what facts in its documents are at issue. RB Health also improperly filed an RJN with its reply, as well as another RJN weeks after the briefing was complete, seeking to introduce a document that appears to be key in assessing its preemption argument without leave of court and without showing good cause. Given the identified problems with RB Health's RJNs, as well as the parties' disputes about the meaning and relevance of the materials, the court declines to take judicial notice of any of the documents submitted by the parties. *See Khoja*, 899 F.3d at 999, 1000. Moreover, given the nature of the disputes identified by the parties in their briefing and RJN submissions, the court concludes that the preemption issue is more appropriate for a motion for summary judgment, on a full record that walks through the relevant evidence regarding the history of the products' packaging and any FDA approvals thereof. That portion of the motion for judgment on the pleadings is accordingly denied without prejudice to RB Health raising this issue at summary judgment.

2. Whether DiGiacinto Makes "Deceptive by Implication" Claims

RB Health also moves for judgment on the pleadings on the ground that California law does not allow "deceptive by implication" claims like those at issue here. Mot. 14. It argues that DiGiacinto's claims "seek to impose liability based on an entirely true representation by virtue of what it 'implies' about other products not referenced on the label and that may or may not be sold in proximity or even in the same store." Mot. 14. According to RB Health, such claims are not actionable under *Shaeffer v. Califia Farms, LLC*, 44 Cal. App. 5th 1125, 1139 (2020). *Id.*

[2] For his part, DiGiacinto submitted a request for judicial notice in which he asks the court to take judicial notice of nine documents that he claims are relevant to his opposition. [Docket No. 60-2 (P's RJN).] DiGiacinto does not explain the relevance of these materials and, like RB Health, does not identify which facts in the materials are judicially noticeable. RB Health opposes DiGiacinto's request on the ground that the materials are not relevant. [Docket No. 62-2.]

In *Shaeffer*, the plaintiff challenged as misleading the label on "Cuties Juice," a tangerine juice product. The label stated "100% Tangerine Juice," "No Sugar Added," and "Never From Concentrate." *Id*. at 1132. Even though it was true that Cuties Juice had "No Sugar Added," the plaintiff alleged that the statement was nevertheless fraudulent because it was "likely to deceive reasonable consumers in its implications." Such implications include that competing brands do contain added sugar, "such that Cuties Juice 'contain[s] less sugar than competing brands that did not have sugar-content claims on their front labels," and that "Cuties Juice is therefore 'different and healthier than . . . competing tangerine juice.'" *Id*. at 1132-33 (citations omitted). Because competing brands did not contain added sugar, the plaintiff alleged that the Cuties Juice label constituted a fraudulent business practice, untrue or misleading advertisement, and unfair method of competition. *Id*. at 1133.

The court discussed the spectrum of labeling statements that are "likely to deceive" a "reasonable consumer" and thus are actionable under state law. *Id*. at 1137-39. At one end of the spectrum are untrue affirmative statements about a product on its label that are by definition "fraudulent" and "false." *Id*. at 1138. "[A]t the far end of the spectrum are statements a business affirmatively and truthfully makes about its product and which do not on their face mention or otherwise reference its competing products at all." *Id*. at 1139. The court found that "whether a truthful statement about one's own product is actionable turns on whether a reasonable consumer is (1) likely to infer from such a statement that the very same statement is untrue as to comparable, competing products, (2) likely to infer that the product at issue is consequently superior to its competition, and (3) likely to be deceived if the statement is *true* as to the comparable, competing products?" *Id*. (emphasis in original). The court held that such statements, including the statement "No Sugar Added" on the Cuties Juice label, are not actionable as a matter of law in part because "a reasonable consumer is unlikely to make the series of inferential leaps outlined above." *Id*. The court explained that it was "hesitant to adopt a theory upon which almost any advertisement [truthfully] extolling a product's attributes would be fodder for litigation." *Id*. (cleaned up).

RB Health argues that DiGiacinto's claims "are even more attenuated than those in

Shaeffer." Mot. 15. It argues that DiGiacinto's claims are based on the allegations that a reasonable consumer viewing the word "children" on the children's product label would believe it implies that the children's product "is a superior product for children as compared to" the adults' product, and that the adults' product is not for children. *Id*. However, it argues, the label of the children's product contains no references to the adults' product, and the packaging of both products shows that the ingredients and concentrations are the same. Accordingly, RB Health argues, DiGiacinto's claims fail as a matter of law. *Id*.

RB Health misapprehends DiGiacinto's allegations about the labels at issue. DiGiacinto alleges that the children-specific representations on the children's product, including the word "Children's," the cartoon image of a child, and statement "Ages 4+," caused him and reasonable consumers to believe that the children's product is "specially formulated for children," even though it is not. *See* FAC ¶ 26. "This inference is a much smaller 'leap' than the one in *Shaeffer* and has nothing to do with practices by competitors." *See Adams v. Starbucks Corp.*, No. SACV 20-00225 JVS (KESX), 2020 WL 4196248, at *4 (C.D. Cal. July 9, 2020) (holding that inference made by consumer "who sees a menu board with different calories and prices for larger sizes of the same product" was "simple—that buying the same coffee drink in a larger size from the same company would mean she would get more coffee and more caffeine."); *Scilex Pharms. Inc. v. Sanofi-Aventis U.S. LLC*, No. 21-CV-01280-JST, 2021 WL 11593043, at *12 (N.D. Cal. Aug. 16, 2021) (holding that allegations that defendants' advertising and marketing is likely to deceive a reasonable consumer to believe that "Defendants' patches offer 'the maximum amount of lidocaine available in patch form' and 'adhere to the skin and provide pain relief for periods of 8 or 12 hours . . . do not require any 'inferential leaps'"). Ultimately, the Ninth Circuit has cautioned that the reasonable consumer standard "raises questions of fact" and that it is only in "rare situations" that such questions should be resolved on the pleadings. *See Reid v. Johnson & Johnson*, 780 F.3d 952, 958 (9th Cir. 2015) (quotation marks and citation omitted). The court concludes that the FAC adequately alleges how RB Health's labeling has "the capacity, likelihood or tendency to deceive or confuse the public." *Schaeffer*, 44 Cal. App. 5th at 1135. This portion of the motion for judgment on the pleadings is accordingly denied.

II. CONCLUSION

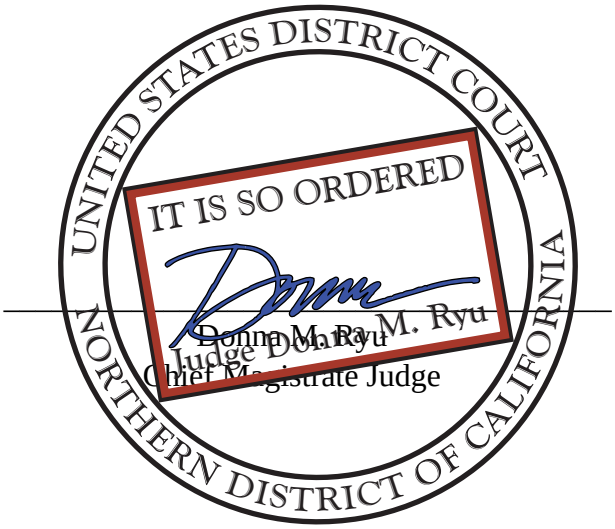
For the foregoing reasons, the court denies the motion for judgment on the pleadings without prejudice to RB Health raising the issue of preemption in its motion for summary judgment.[3] The motion for judgment on the pleadings is denied as to RB Health's argument that DiGiacinto brings "deceptive by implication" claims that are not actionable.

Additionally, DiGiacinto filed an administrative motion to file the exhibits to his RJN under seal and seeks to redact portions of his opposition referring to those materials on the ground that RB Health designated the exhibits as confidential pursuant to the parties' stipulated protective order. [Docket No. 58.] RB Health filed a corresponding motion to strike or seal portions of the exhibits attached to DiGiacinto's RJN. [Docket No. 63.] The parties' administrative motions to seal are denied as moot, as the court did not rely on the sealed materials in deciding this motion.

Finally, the parties filed a joint discovery letter on October 20, 2023 regarding their dispute about whether discovery should be stayed pending the court's ruling on the motion for judgment on the pleadings. [Docket No. 75.] Given the court's ruling on the motion, the joint discovery letter is denied.

IT IS SO ORDERED.

Dated: October 30, 2023



[3] RB Health's RJNs consisted of separate multiple-page briefs, as did DiGiacinto's own RJN, the parties' objections to the RJNs, and RB Health's reply in support of its original RJN. These submissions resulted in the parties' briefs going beyond applicable page limits. In future motions, the parties should include any argument supporting or opposing requests for judicial notice within the main briefs.